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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/685,333 | 10/14/2003 | Scott T. Moore | 10000-231 | 1212 |

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| EXAMINER | |
|---|---|
| SNOW, BRUCE EDWARD | |
| **ART UNIT** | **PAPER NUMBER** |
| 3738 | |

DATE MAILED: 02/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/685,333 | MOORE, SCOTT T. | |
| | Examiner | Art Unit | |
| | Bruce E Snow | 3738 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *26 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *29 and 30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28 and 31-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/2/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election of Species 1 in Paper No. 01262005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicant has not given reasons why the species are not patentably distinct and, therefore, it is the Examiner's position that applicant has not traversed the election of species requirement. The requirement is deemed proper and is therefore made FINAL.

Claims 29-30 (species shown in figures 5-6) are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species,

### *Specification*

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: "the remaining section of the stent introducer apparatus and introducer catheter" (claim 24).

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-14, 15-23, 21-23, 33-34, 31, 36-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's specification does not support the use of polytetrafluoroethylene for the pusher member and does not teach a radiopaque filler material.

Regarding claim 15, the stent held tightly between the distal tip and pusher member is not taught in the specification and clearly not shown in the drawings.

Claim 31, the introducer having sections of varying resiliencies is new matter.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 is not understood.

Claim 31 is not understood. Is the introducer catheter now being positively claimed? What are the sections of varying resiliencies?

Claims 36-40, regarding claim 36, "the pusher member being located distal to the second tubular portion" is not correct. Please use the drawings and specification to clarify if applicant disagrees with the Examiner.

Claim 40, it is unclear how the distal end conforms to the stent. As shown in figure 1, the distal end does not conform to the stent.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1-7, 11, 24-28, 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Ravenscroft (5,702,418).

Ravenscroft teaches a stent delivery system comprising:

a pusher assembly that includes first tubular portion including element 15 having a second diameter; a second tubular portion beginning with element 16 and including a flexible portion 17 which has a greater degree of flexibility than said first tubular portion and having a first diameter, the second diameter is greater than the first diameter; said

second tubular portion further comprising a stent loading portion and a pusher members 23 wherein the proximal member is fully capable of engaging a proximal end of a stent (claim 1).

Regarding at least claim 3, see figure 3. The pusher member has a diameter equal to or greater than the stent at 20b.

Regarding at least claim 11, distal tip, see element 13.

See introducer 24.

Regarding the "second member" is see element 16.

Regarding claim 27, the proximal surface of the pusher member would inherently open any kinks upon removal.

Regarding claim 31, the resiliency changes as a function of length and position.

All other claim limitations are self-evident.

Claims 1-13, 14-21, 23-28, 31-32, 34-36, 38-40 are rejected under 35 U.S.C. 102(e) as being **clearly anticipated** by Wilson et al (6,425,898).

Wilson teaches a stent delivery system comprising:

a pusher assembly that includes first tubular portion 16 and a second tubular portion 18 which has a greater degree of flexibility than said first tubular portion (see at least 5:15-44; pusher member 21, 22; outer sheath 40; second member 17.

Regarding the second tubular member portion having a smaller diameter, see figure 5, showing the first tubular portion 16 which includes a larger diameter portion between reference numerals 5 and 16.

Regarding claim 15, the stent is tightly held between the distal tip and face of the pusher member expanding against the sheath.

All other claim limitations are self-evident.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12-13, 21-22, 32-33, 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ravenscroft (5,702,418).

Ravenscroft teaches a stent delivery system as described above, however, fails to teach the pusher member is made of a polymer and the polytetrafluoroethylene. It would have been obvious to one having ordinary skill in the art to have made the pusher member of Ravenscroft from a polymer and further made it from polytetrafluoroethylene because they are well known biocompatibility, moldability, and low friction property.

Additionally, the use of a polymer and polytetrafluoroethylene (PTFE) for the pusher member lacks any criticality of the specification producing no stated advantage and is considered an obvious matter of design choice.

Claims 13, 22, 33, 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al (6,425,898).

Wilson et al teaches a stent delivery system as described above including the pusher member is made of a polymer. However, Wilson et al fails to teach the pusher member is made of polytetrafluoroethylene. It would have been obvious to one having ordinary skill in the art to have made the pusher from polytetrafluoroethylene because of its well known biocompatibility, moldability, and low friction property.

Additionally, the use of polytetrafluoroethylene (PTFE) for the pusher member lacks any criticality of the specification producing no stated advantage and is considered an obvious matter of design choice.

Claims 1-28, 31-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ravenscroft (5,702,418) in view of Wilson et al (6,425,898).

Ravenscroft teaches a stent delivery system as described above. However, Ravenscroft fail to teach the wherein the pusher member includes a radiopaque filler material. Wilson et al teaches a pusher member 21, 22 includes a radiopaque filler. It would have been obvious to one having ordinary skill in the art to have substituted the pusher member configuration of Wilson et al for that of Ravenscroft which is includes a radiopaque material which can be viewed in the body during surgery and the configuration "*also aids in positioning the stent within the target lesion during deployment within a vessel*" (see column 6, lines 19-21). Note that the combination produces a different configuration which rejects additional claims including claim 1.

Regarding the use of polyimide, see 5:29 of Wilson et al.

Regarding at least claims 8-10, see 5:27 of Wilson et al.

Regarding the use of polytetrafluoroethylene (PTFE) for the pusher member lacks any criticality of the specification producing no stated advantage and is considered an obvious matter of design choice.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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BRUCE SNOW
PRIMARY EXAMINER